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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,149	08/16/2005	Bihui Wang	18200-002US1	8974

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EXAMINER	
CHEN, CATHERYNE	
ART UNIT	PAPER NUMBER
1655	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/507,149	WANG ET AL.	
	Examiner	Art Unit	
	Catheryne Chen	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-16 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-16 is/are rejected.

7)☒ Claim(s) 13 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Currently, Claims 1-16 are pending.

Specification

The abstract of the disclosure is objected to because it is more than 150 words. Correction is required. See MPEP § 608.01(b).

Claim Objections

Claim 13 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot reference two sets of claims to different features. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The terms "for available" in steps 4b and 4c are not coherent or comprehensible. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 12, 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yanaki et al. (US 5538728), Guo (CN 1051236 C), Song et al. (CN 1202361 A), Tao (US 6383524 B2).

Applicant's claim is drawn to sanguis draxonis, radix paeniae rubra, indigo naturalis, halloysitum rubrum, catechu, calcined alumen, rhizome bletillae, calamine for enema.

Yanaki et al. teaches alumina, which is alumen (column 1, line 44), peony, which is paeniae (column 13, line 54), kaolin, which is halloysitum (column 29, line 48), for rectal administration preparation (column 9, line 46) as a laxative (column 8, line 55). However, it does not teach the other compounds.

Guo teaches hyacinth bletillae, calamine for stopping bleeding and pain of internal and external injuries (abstract).

Song et al. teaches natural indigo, catechu for inflammatory enteropathy (abstract).

Tao teaches Daemonorops or xuejie, which is sanguis draxonis, (column 1, line 61; column 2, line 13) for internal bleedings (column 11, line 42).

The reference also does not specifically teach combining all of the claimed components together. The reference does teach that the compounds are useful for treating internal bleedings or inflammations (see Yanaki et al., column 9, line 46; Guo and Song et al., abstracts; Tao, column 11, line 42). As discussed in MPEP 2144.06:

It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art.

Thus, is would be obvious to combine the compounds above for treating rectal or internal bleeding medical conditions because they are taught in the reference to have the same purpose.

The references also do not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine

practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Claim 4-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yanaki et al. (US 5538728), Guo (CN 1051236 C), Song et al. (CN 1202361 A), Tao (US 6383524 B2), Shastri et al (US 4017615), and Verge et al. (US 5800817).

Applicant's claim is drawn to sanguis draxonis, radix paeniae rubra, indigo naturalis, halloysitum rubrum, catechu, calcined alumen, rhizome bletillae, calamine for enema with the methods of preparing the materials.

See above for discussion for Yanaki et al., Guo, Song et al., and Tao. However, they do not teach the steps for preparing the materials.

Tao teaches extracting composition with aqueous solution at different temperatures, mixing the substances in dried powder form, any method or conditions known in the art to yield extracts comparable in effectiveness in enhancing therapeutic effects (column 8, lines 50-51, 55, 57-59; column 9, lines 1-5).

Verge et al. teaches methods of processing plant material with cleaning, macerating, extracting solutions with water, with time durations and

temperatures, separating liquid extracts from plant residues (column 2, lines 1, 16-17, 32-33, 36-37, 39-40; column 3, line 62-63; column 4, 44; column 5, lines 22-24), allowed to cool, particle size of 0.1mm (column 5, lines 28, 30-31), for use rectally (column 5, line 47-48).

Shastri et al. teaches polyethylene glycol 400, tragacanth, and potassium sorbic acid for medical ointments (column 3, line 62; column 4, lines 24, 38-43).

The reference also does not specifically teach combining the materials and steps in the specific order together. The reference does teach that any method or conditions known in the art to yield extracts comparable in effectiveness in enhancing therapeutic effects (see Tao, column 9, lines 1-5).

As discussed in MPEP 2144.06:

It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art.

Thus, is would be obvious to combine the materials with the steps for creating an ointment because they are taught in the reference to have the same purpose.

The references also do not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable

ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

The reference also does not specifically teach formulating the composition in the forms claimed by applicant and using PEG 400, tragacanth, and potassium sorbate. These pharmaceutical forms are well known in the art to be acceptable means of administering a pharmaceutically active substance as an ointment. Based on this knowledge, a person of ordinary skill in the art would have had a reasonable expectation that formulating the composition taught by the references in the claimed forms would be successful. Therefore, an artisan of ordinary skill would have been motivated to formulating the composition taught by the reference in the forms claimed by applicant. In addition, while the reference does specifically claim using PEG 400, tragacanth, and potassium sorbate, the reference does teach using pharmaceutically acceptable solvents, excipients, and filler. PEG 400 is a well known pharmaceutical carrier (Verge et al., column 5, line 63-65). Tragacanth is a well known pharmaceutical thickener (Shastri et al., column 4, lines 18-24). Potassium sorbate is a well known pharmaceutical

preservative (Shastri et al., column 4, lines 38-43). Thus, a person of ordinary skill in the art would reasonably expect that medical ointments for use as an enema contained in the claimed compounds could be used in the composition of the reference.

Conclusion

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catheryne Chen whose telephone number is 571-272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Catheryne Chen
Patent Examiner
Art Unit 1655

11-15-06
SUSAN COE HOFFMAN
PRIMARY EXAMINER